

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 39-98 are pending in the application, with claim 39 being the independent claim. Claims 89-98 have been added. Claims 39, 45, 46, 85, and 87 have been amended. Support for the amendment may be found throughout the specification. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Information Disclosure Statement

Applicants respectfully request consideration of the IDS filed May 23, 2003, and making the documents listed therein of record in the present application. Courtesy copies of the IDS are submitted herewith for the Examiner's convenience.

Objection to the Specification

The abstract was objected to for containing the original title of the application. Applicants submit herewith a replacement page containing the abstract without any title, as suggested by the Examiner. Accordingly, the objection has been rendered moot.

Objection to the Drawings

The drawings were objected to for allegedly having half-tone photographs and having views not numbered consecutively. Applicant submits herewith corrected drawings to overcome the objection. The copies provided are the darkest copies that could be obtained from the original drawings. Accordingly, the objection has been rendered moot.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 39-84, 86 and 88 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly being nonenabled. (Paper 9, p. 3). The Office Action stated that the recitation of "recovering those host cells which have undergone a lytic event," renders the claims non-enabled because they encompass recovering lysed host cells. (*Id.*). Applicant respectfully traverses.

To be enabled for their full scope, claims need not include limitations concerning factors that are within the level of ordinary skill in the art. *In re Skrivan*, 427 F.2d 801, 806 (CCPA 1970); MPEP § 2164.08. Further, a specification needs not teach what is well known in the art. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In the present case, the claims are directed to the selection of a nucleic acid that encodes a cytotoxic T cell epitope of interest, as recited in the preamble to claim 39. As noted in the Office Action, the specification provides an example in which a monolayer of cells was contacted with CTLs, causing cells that contain the desired recombinant(s) to

undergo a lytic event, and to lift off the monolayer. These floating cells were recovered by washing the monolayer and separately harvesting the floating cells from the adherent cells.¹

The vaccinia vectors used in the present invention package in the cell cytoplasm. Therefore, if a sufficient amount of time is allowed to pass before the cells that are undergoing a lytic event are recovered, they would begin to lyse and the cell contents including the recombinant virus would be released into the cell culture medium. Released virus could be recovered along with the other constituents of the lysed host cells in a manner similar to or the same as that for the floating cells, for example, by simply collecting the tissue culture medium.² In other words, whether the recombinant, replication competent virus were contained in host cells -- *or not* -- either way, the virus could be recovered, for example, by collecting the cell culture medium.³ Claim 39 and the dependent claims therefore achieve the purpose recited in the claim 39's preamble, i.e., selection of nucleic acids encoding the recited epitope.

Accordingly, the claims are fully enabled. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

¹ Applicant notes that other methods for recovering cells undergoing a lytic event, such as cell sorting, for example, were known prior to the filing date, and need not have been taught in the specification. "To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for 'preferred' materials . . . would not serve the constitutional purpose of promoting progress in the useful arts." *In re Goffe*, 542 F.2d 564, 567 (CCPA 1976); MPEP § 2164.08.

² Furthermore, no purification of the recombinant virus away from the recovered host cells or cell constituents is needed. It is well known in the literature the all that is needed to is to plate the recovered cells or cell constituents on a fresh monolayer because the recombinant virus is the only constituent that grows. If purification is desired, it can be accomplished simply by picking plaques.

³ In addition, several other methods of recovering lysed cell constituents such as released virus were known when the present application was filed.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 39-44 and 46-88 were rejected under 35 U.S.C. § 112, second paragraph for allegedly failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. (Paper 9, p. 4). The Office action stated that claim 39 was incomplete for failing to recite a "resolution step" for selecting the nucleic acid. Applicant respectfully traverses.

Applicant has amended claims 39 and 46 to recite "(b) recovering vector from said host cells."⁴ Applicants respectfully believe the amendment obviates the rejection. Accordingly, reconsideration and withdrawal are respectfully requested.

Non-statutory Double Patenting Rejection

Claims 39-88 were provisionally rejected under the doctrine of obviousness-type double patenting over claims 68-70, 79-91, 89-100, and 104-120 of U.S. Application number 08/935,377. Applicant respectfully traverses.

Applicants submit herewith a Terminal Disclaimer to obviate the rejection. Accordingly, the rejection has been rendered moot. Applicants reserve the right to address the rejection on the merits at a future time.

⁴ Applicant again notes that purification of the viral nucleic acid from the host cell is not needed, as the virus can be plated on a fresh monolayer without having been purified first. Moreover, if purification is desired, one could simply pick plaques.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant(s) therefore respectfully request(s) that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant(s) believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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